JUN 3 0 2000 **Summary of Safety and Effectiveness**

April 10, 2000

K001322

I. **Device Submitted:** CO_2 laser and accessories

II. **Proprietary Name:** Performer 30 HPS

III. **Common Name:** CO_2 Laser

IV. **Predicate Device:** Sharplan CO_2 Surgical Laser, K933362

General Project's Performer 30 HPS is substantially equivalent to the Sharplan CO_2 Surgical Laser imported and distributed by Sharplan Lasers Inc. of Allendale, NJ and manufactured by Laser Industries, Inc. of Tel Aviv, Israel.

V. **Device Description:**

The Performer 30 HPS is a microprocessor controlled laser system which uses a sealed off CO_2 laser tube that produces a 10.6 micron wavelength of infrared energy. The main parts of the system include a housing cabinet for the CO_2 laser tube, an articulated arm for beam delivery, a footswitch to activate and control the laser emission and assorted laser accessories.

VI. **Intended Use:**

The Performer 30 HPS is intended to be used for, excision, incision, vaporization, and coagulation of soft tissue in plastic surgery, gynecological surgery, dermatological surgery, ENT surgery, neurological surgery, and general and aesthetic surgery.

VII. **Technological Characteristic Similarities:**

Performer 30 HPS is similar in intended use and mode of operation to the Sharplan CO_2 Surgical Laser. Both devices utilize a microprocessor controlled carbon dioxide laser system, an articulated arm, a handpiece, and a footswitch for laser emission control. The intended uses of the Performer 30 HPS and the Sharplan CO_2 laser are the same in that both devices are for incision/excision, vaporization and coagulation of soft tissue in plastic surgery, dermatological surgery, gynecological surgery, ENT surgery, neurological surgery and general and anesthetic surgery.

VIII. **Performance Data:**

No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A data base search has been performed to evaluate any adverse effects of the device that is currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c)] See attached documentation of adverse effects.

SUMMARY:

Beginning with the year, 1966, to the present, a database search of the adverse safety and effectiveness reported with use of a CO_2 laser for incision, excision, vaporization, and coagulation of soft tissue in plastic surgery, gynecological surgery, dermatological surgery, ENT surgery, neurological surgery, and general and aesthetic surgery was carried out. The results of the database search are located in Appendix F.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

General Project
c/o Ms. Cornelia Damsky
Regulatory Consultant
Cornelia Damsky, Inc.
56 Westcott Road
Stamford, Connecticut 06902

Re: K001322
Trade Name: Performer 30 HPS
Regulatory Class: II
Product Code: GEX
Dated: April 20, 2000
Received: April 26, 2000

Dear Ms. Damsky:

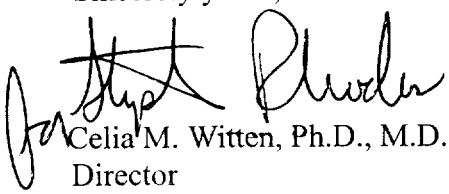
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K001322

Performer 30 HPS

This product is intended to be used by surgeons for the incision, excision, and vaporization of soft tissue in the following:

- Plastic surgery
- Gynecological surgery
- Dermatological surgery
- ENT surgery
- Neurological surgery, and
- General and aesthetic surgery

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001322